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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,430	01/17/2006	Stefan Werner	049202/303874	1581
826 7590 03/12/2009				
ALSTON & BIRD LLP				
BANK OF AMERICA PLAZA				
101 SOUTH TRYON STREET, SUITE 4000				
CHARLOTTE, NC 28280-4000				
EXAMINER				
FOX, DAVID T				
ART UNIT		PAPER NUMBER		
1638				
MAIL DATE		DELIVERY MODE		
03/12/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,430

Applicant(s)

WERNER ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on papers filed 13 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 12-19 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) 14-17, 21-29, 35 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 12, 13, 18, 19, 30-34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's Response

Applicant's amendments of 13 January 2009 have overcome the specification objections, the indefiniteness and written description rejections, and the art rejections of record. The enablement rejection has been withdrawn-in-part based upon Applicant's amendments, as discussed below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objection

Claims 18-19 remain objected to for encompassing non-elected subject matter, namely replicating RNA molecules.

Request for Rejoinder

Applicant requests that claims 24-25 and 27-29 be rejoined, asserting that there would be no undue burden to search or examine these claims, because they depend upon claims previously examined. The Examiner maintains that the subject matter of these claims, namely sequences conferring seed or seedling sterility in the F1 progeny generation, sequences encoding enzymes which alter plant hormone production and thus hinder mature plant development, and methods for evaluating seed or seedling sterility; were not examined and would constitute an additional burdensome search and examination.

Indefiniteness

Claims 2, 30 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 30 and 34 are indefinite in their recitation of "said product of interest" which lacks antecedent basis in amended claim 2, or in amended claim 1 on which claims 30 and 34 depend.

Replacement of "product" with ---protein--- in claim 2, part (a), penultimate line; claim 30, line 1; and claim 34, line 2 would obviate this rejection.

Enablement

Claims 1-2, 12-13, 18, 30-34 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to methods for plant transformation with plant geminiviral origins of replication and replicase genes, does not reasonably provide enablement for claims broadly drawn to plant transformation with animal geminiviral sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 7-10 of the last Office action.

Applicant's arguments filed 13 January 2009 have been fully considered but they are not persuasive. Applicant urges that the claim amendments to recite "plant geminiviral" sequences, recombinase systems, and replicase protein-encoding genes,

obviate the enablement rejection. The Examiner maintains that only claim 19 is limited to plant geminiviral sequences.

Amendment of claims 1-2 to insert ---plant--- before "geminiviral", each occurrence; and cancellation of claim 19, would obviate this rejection.

Anticipation

Claim 36 is rejected under 35 U.S.C. 102(e) as being anticipated by Lyznik et al (US 7,164,056, effectively filed 03 May 2002).

The claim is drawn to a seed "producible" by the process of claim 1. Claim 1 recites a method for crossing a first plant comprising a protein-encoding gene and a geminiviral replicon comprising a geminiviral origin of replication and a geminiviral replicase gene, with a second plant comprising a recombinase gene, to produce F1 seed, followed by extraction from the seed of the protein encoded by the gene. The F1 seed would comprise in its genome the protein-encoding gene, the complete geminiviral replicon, and the recombinase gene.

Lyznik et al teach a seed comprising a protein-encoding gene, a geminiviral origin of replication and geminiviral replicase gene, additionally comprising a recombinase gene, as discussed on page 20 of the last Office action.

The seed taught by Lyznik et al, comprising all of the genetic components of the seed produced by the method of claim 1, would have been indistinguishable from the seed produced by the method of claim 1, even though the methods used to produce the seeds were different.

See *In re Best* and *In re Thorpe* cited previously.

Claims 1-2, 12-13, 18-19, 30-34 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Yadav et al (US 6,632,980 filed 17 November 1999).

The claims are drawn to a method of crossing a first plant comprising a protein-encoding gene and a geminiviral replicon comprising a geminiviral origin of replication and a geminiviral replicase gene, with a second plant comprising a recombinase gene, to produce F1 seed comprising a replicating DNA comprising the replicon, protein-encoding gene and recombinase-encoding gene; followed by extraction from the seed of the protein encoded by the gene; wherein the geminivirus may be a plant geminivirus, wherein the protein may be foreign to the plant, wherein monocots or dicots may be employed, wherein an autonomous plasmid is generated by the combination of the geminiviral replicon and the recombinase gene into a single plant genome, wherein the transcription of the gene(s) involved in the production of the replicating DNA may be controlled by a chemically regulated or seed-specific promoter, wherein the protein accumulates in seed or embryo/endosperm tissue as the result of the production of the replicating DNA, and wherein male sterility is used to effect the initial cross between the two plants.

Yadav et al teach a method of crossing a first plant comprising integrated into its chromosomal genome a protein-encoding gene and an "inactive" plant geminiviral replicon comprising an origin of replication and inherently comprising a replicase gene, with a second plant comprising a recombinase-encoding gene, wherein the seed and progeny of said cross comprise a replicating and autonomous DNA molecule (or "active" geminiviral replicon) as the result of the recombinase-mediated release of the

geminiviral replicon from the chromosomal genome of the first plant, wherein the recombinase-encoding gene may be under the control of a chemically regulated or seed-specific promoter for the production of the replicating DNA molecule specifically in seeds, wherein the protein produced by the protein-encoding gene may be overexpressed and extracted from the seed, wherein the protein may be a foreign protein including seed storage proteins or pest resistance proteins, wherein monocots such as corn and dicots such as tobacco may be employed, and wherein male sterility may be employed in the cross.

See, e.g., Figures 1-2 and 7; claims 1-3, 5-7 and 13; column 10, lines 4-37; column 14, lines 30-34 and 59-64; column 15, lines 36-56; column 16, lines 28-34; column 17, lines 10-17; column 18, lines 5-7 and 46-61; column 20, line 54 through column 21, line 10; column 22, lines 33-35; column 24, line 6 through column 25, line 28; column 26, lines 35-48; column 32, lines 9-20; column 33, lines 30-42; column 36, line 12 through column 37, line 1.

Allowable Subject Matter

Amending the claims to recite that the first and second plant each comprise a gene encoding a portion of the protein of interest, in addition to the geminiviral replicon and recombinase gene, wherein neither the first nor the second plant comprise the entire protein of interest; if basis exists for same; would obviate the art rejections above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David T Fox/

Primary Examiner, Art Unit 1638

March 10, 2009